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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,128	04/09/2004	Jun E. Lee	IVGN 373	8246

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
03/09/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,128	LEE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 32-82* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,6,8,9,15,55,59,62,64,65,71,76 and 78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2011* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,4,7,10-14,32-54,56-58,60,61,63,66-70,72-75,77 and 79-82.

DETAILED ACTION

Drawings

1. The drawings were received on 14 February 2011. These drawings are acceptable.

Specification

2. The objection to the specification is hereby withdrawn in view of the amendment to same.

Claim Rejections - 35 USC § 112 & 101

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 65, 71, 76, and 78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 55, and 76 are the only independent claims pending and under consideration. Claims 1, 6, and 8 are representative and, for convenience, are reproduced below.

1. (Previously presented) A composition comprising 2 or more different, modified, monomeric deoxyribonucleotide triphosphates, wherein said modified deoxyribonucleotide triphosphates have the ability to bind one or more detectable labels.

6. (Original) The composition of claim 1 further comprising at least one nucleic acid template.

8. (Original) The composition of claim 6, wherein said template is RNA.

6. Attention is directed to MPEP 904.01.

> The breadth of the claims in the application should always be carefully noted; that is, the examiner should be fully aware of what the claims do not call for, as well as what they do require. During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See In re Morris, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997). See MPEP § 2111 - § 2116.01 for case law pertinent to claim analysis.

7. It is noted with particularity that narrowing limitations found in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. In re Philips Industries v. State Stove & Mfg. Co, Inc., 186 USPQ 458 (CA6 1975). While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into the claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See Ex parte Oetiker, 23 USPQ2d 1641 (BPAI, 1992).

8. Attention is directed to MPEP 2163.04:

> A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may also be subject to rejection under 35 U.S.C. 112, para. 1, as not enabling, or under 35 U.S.C. 112, para. 2. See In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976); In re Venezia, 530 F.2d 956, 189

> USPQ 149 (CCPA 1976); and In re Collier, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). See also MPEP § 2172.01.

9. The claimed composition (claims 1, 3, 5, 6, 8, 9, and 15), kit (claims 55, 62, 64, 65, and 71), and reaction mixture (claims 76 and 78) have been construed as encompassing any nucleic acid material, including, but not limited to the elected species of RNA. Support for this interpretation is based in part on the positive recitation that the composition and kit are to comprise same. Further, the specification at page 23, paragraph [0055], states,

> Nucleic acid templates suitable for reverse transcription according to this aspect of the invention include any nucleic acid molecule, particularly those derived from a prokaryotic or eukaryotic cell. Such cells may include normal cells, diseased cells, transformed cells, established cells, progenitor cells, precursor cells, fetal cells, embryonic cells, bacterial cells, yeast cells, animal cells (including human cells), avian cells, plant cells and the like, or tissue isolated from a plant or an animal (e.g., human, cow, pig, mouse, sheep, horse, monkey, canine, feline, rat, rabbit, bird, fish, insect, etc.). Such nucleic acid molecules may also be isolated from viruses.

Utility of the claimed composition, kit and reaction mixture resides in the product produced, i.e., cDNA. Not all mRNA, or cDNA has utility. Utility of the claimed composition/kit/reaction mixture is deemed to be a lynchpin to patentability. Accordingly, the claims have not been construed as requiring the "template" be any nucleic acid that has a specific, substantial, and credible utility or a well-established utility.

10. As set forth in In re Alonso 88 USPQ2d 1849 (Fed. Cir. 2008), at 1851:

> The written description requirement of 35 U.S.C. § 112, ¶ 1, is straightforward: "The specification shall contain a written description of the invention …." To satisfy this requirement, the specification must describe the invention in sufficient detail so "that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997); see also LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 [76 USPQ2d 1724] (Fed. Cir. 2005); Eiselstein v. Frank, 52 F.3d 1035, 1039 [34 USPQ2d 1467] (Fed. Cir. 1995).

Alonso at 1852:

> A genus can be described by disclosing: (1) a representative number of species in that genus; or (2) its "relevant identifying characteristics," such as "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Enzo, 323 F.3d at 964.

11. In applying the test as set forth in Alonso, it is noted that applicant is claiming a genus of compositions, reaction mixtures and kits that encompass any nucleic acid. A review of the disclosure fails to find where applicant has provided any Sequence Listing or has otherwise provided an adequate written description of those nucleic acids that have utility over those that do not. Further, the records does not establish that applicant had possession of the compositions and reaction mixtures, or the kit, that comprises any and all manner of nucleic acid templates, be they RNA or not.

12. Such non-disclosure by applicant does not reasonably satisfy either prong of the written description test as set forth in Alonzo as applicant has not provided "(1) a representative number of species in that genus; or (2) its 'relevant identifying characteristics,' such as 'complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'"

13. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in University of California v. Eli Lilly and Co. (Fed. Cir. 1997) 43

USPQ2d at 1405, citing Lockwood v. American Airlines Inc. (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

14. For the above reasons, and in the absence of convincing evidence to the contrary, the claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 65, 71, 76, and 78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Response to argument

15. At pages 12-13 of the response of 14 February 2011, hereinafter the response, argument is presented that the claims are not directed to any mRNA or DNA, and thusly, satisfy the written description requirement.

16. The above argument ahs been considered and has not been found persuasive as dependent claims 6 and 62 explicitly require "at least one nucleic acid template" and dependent claims 8, 9, 64 and 65 specifically require the template to be mRNA or "a population of mRNA molecules." Claim 15, which depends from claims 6, 8, and 9; and claim 71, which depends from claims 62, 64, and 65, by default, comprise the limitations of claims that they depend from. Further, given that said claims depend from either independent claim 1 or 55, said independent claims 1 and 55 must encompass more than just those limitations, else, claims 1 and 55 would not be further limited by the dependent claims (requirement under 35 USC 112, fourth paragraph).

17. Applicant has not presented argument as to how use of the name "template" and "mRNA" constitutes an adequate written description of the genus of molecules that are encompassed by the claims.

Attention is directed to the decision of Fiers v. Sugano 25 USPQ2d 1604-5 (CAFC, January 1993) wherein is stated:

> We also reject Fiers argument that the existence of a workable method for preparing a DNA establishes conception of that material. Our statement in Amgen that conception may occur, inter alia, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. We recognize that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute conception of the substance claimed as a process. Conception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties. . .
> * * * *
> The difficulty that would arise if we were to hold that a conception occurs when one has only an idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions.

Attention is also directed to the decision of University of California v. Eli Lilly and Co. (CA FC, July 1997) 43 USPQ2d 1398 wherein is stated:

> In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d

> 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.
>
> Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

18. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection of claims under 35 USC 112, first paragraph, for failing to satisfy the written description requirement is maintained.

19. Claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 65, 71, 76, and 78 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

20. Attention is directed to MPEP 904.01.

> The breadth of the claims in the application should always be carefully noted; that is, the examiner should be fully aware of what the claims do not call for, as well as what they do require. During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See In re Morris, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997). See MPEP § 2111 - § 2116.01 for case law pertinent to claim analysis.

21. It is noted with particularity that narrowing limitations found in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. In re Philips Industries v. State Stove & Mfg. Co, Inc., 186 USPQ 458 (CA6 1975). While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into the claims. On the contrary, claims must be

interpreted as broadly as their terms reasonably allow. See Ex parte Oetiker, 23 USPQ2d 1641 (BPAI, 1992).

22. Utility of the claimed composition, kit and reaction mixture resides in, or downstream of, the product produced, i.e., cDNA being used to diagnose a specific condition or to produce a protein that has utility. Not all mRNA, or cDNA derived therefrom, has utility. Utility of the claimed composition/kit/reaction mixture is deemed to be a "linchpin" to patentability. Accordingly, the claims have not been construed as requiring the "template" be any nucleic acid that has a specific, substantial, and credible utility or a well-established utility.

23. Claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 65, 71, 76, and 78 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to argument

24. At pages 13-14 of the response argument is presented that the claimed invention does have utility, and asserts further that "a utility of a naturally- occurring full-length nucleotide sequence when isolated in its entire length, is well- established."

25. The above argument has been considered and has not been found persuasive. As an initial matter, applicant's arguments are conclusory in nature and void of any factual underpinning. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.

> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

26. It is further noted that applicant is arguing limitations not recited in any of the claims under consideration, as no claim requires the mRNA to be a "naturally-occurring full-length nucleotide sequence."

27. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 65, 71, 76, and 78 remain rejected under 35 USC 101, and also remain rejected under 35 U.S.C. 112, first paragraph.

28. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

29. The term "modified" in claims 1, 55, and 76 is a relative term which renders the claims indefinite. The term "modified" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 3, 5, 6, 8, and 9, which depend from claim 1; claims 62, 64, 65, and 71, which depend from claim 55; and claim 78, which depends from claim 76, fail to overcome this issue and are similarly rejected.

30. The term "different" in claims 1, 55, and 76 is a relative term which renders the claims indefinite. The term "different" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be

reasonably apprised of the scope of the invention. Claims 3, 5, 6, 8, and 9, which depend from claim 1; claims 62, 64, 65, and 71, which depend from claim 55; and claim 78, which depends from claim 76, fail to overcome this issue and are similarly rejected.

31. The term "detectable" in claims 1, 55, and 76 is a relative term which renders the claims indefinite. The term "detectable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is further noted that all matter, including a black hole, is detectable, be it directly or indirectly. Accordingly, the use of the adjective "detectable" to modify "label" clouds the aspect of just what the metes and bounds of the claims are. Claims 3, 5, 6, 8, and 9, which depend from claim 1; claims 62, 64, 65, and 71, which depend from claim 55; and claim 78, which depends from claim 76, fail to overcome this issue and are similarly rejected.

Response to argument

32. At pages 14-16, applicant reproduces portions of the disclosure that are identified as providing a definition for the terms "different," "detectable" and "modified."

33. Applicant's arguments have been considered and have not been found persuasive. While agreement is reached in that the specification odes address these terms, the definitions provided are exemplary in nature and not limiting. Accordingly, while one may be able to understand that certain embodiments "may be" one thing or another, it does not readily establish just what the limits of the terms are to be. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

34. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

35. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

37. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

38. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634